

## REMARKS

Claims 26 and 27 have been amended to correct a typographical error. Thus, claims 1, 2, 4, 7-12, 16-18, 20 and 23-28 are pending in the present application. No new matter has been added. Reconsideration and withdrawal of the present objection and rejection in view of the comments presented herein are respectfully requested.

### Claim objections

Claims 26 and 27 were objected to based on recitation of “35oC.” Claims 26 and 27 as amended recite the proper term (35°C). Thus, reconsideration and withdrawal of the claim objections are respectfully requested.

### Rejections under 35 U.S.C. § 103(a)

Claims 1, 2, 4, 7-12, 16-18, 20 and 23-28 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gil et al. (*Z Lebensm Unters Forsch A* 208:394-399, 1999 “R1”), in view of Collins et al. (*J. Biol. Chem.*, 277:35133-35139, 2002 “R2”), Gerday et al. (*Trends Biotechnol.* 18:103-107, 2000 “R3”) and Fuglsang et al. (WO 02/19828 “R4”).

Present claims 1, 16 and 17 are directed to compositions and methods for preparing a baked product, and for improving certain properties of a baked product, using at least one glycoside hydrolase Family 8 enzyme with xylanolytic activity obtained from *Pseudoalteromonas haloplanktis*.

As discussed in more detail below, Applicants submit that, due to the considerable variation in the structures and activities of xylanases and to the limited number of xylanases utilized in the baking industry, one skilled in the art would not have a reasonable expectation that the family 8 xylanases from *Pseudoalteromonas haloplanktis* recited in the present claims would be effective in a bread improver composition.

As disclosed by Berrin et al. (*Biotechnol. Lett.* 30:1139-1150, 2008) (Exhibit A), “[T]he heterogeneity and complexity of xylan has resulted in an abundance of diverse xylanases that differ in their physico-chemical properties, structure, mode of action and substrate specificities. A classification system for glycoside hydrolases (GH) has been

established based on amino acid sequence similarities...and, at present, at least 112 different families have been identified... The majority of xylanases cluster into families 10 and 11 but xylanases have also been classified in GH families 5, 7, 8 and 43 ...” Indeed, enzymes with xylanase activity are found in families 5, 7, 8, 10, 11 and 43 (see R2, page 35138, right column, line 25), and, to the best of Applicants’ knowledge, only very few (mainly from family 11), have found an application in the baking industry (Collins et al., *Journal of Cereal Science* 43:79-84, 2006) (Exhibit B). Collins et al. also state that “[d]ue to differences in their substrate specificities, action patterns, interactions with inhibitors and kinetic capabilities, not all xylanases are effective in baking.” Thus, there are hundreds of different xylanases, and only a small fraction of these are suitable for use in the baking industry. Accordingly, the discovery of another particular xylanase capable of use in baked products would be an unexpected result. The amino acid sequence, three-dimensional structure and catalytic residues (amino acids) of the presently claimed family 8 xylanases are very different from those of other xylanases (e.g., family 10 and 11 xylanases). In addition, the family 8 enzymes have unique functional properties, including hydrolyzing with inversion of anomeric configuration.

In view of these extensive differences between family 8 xylanases and other xylanases, it would not be expected that family 8 psychrophilic enzymes would give results that are superior to those obtained with family 11 xylanases.

The choice of one enzyme exhibiting xylanase activity among hundreds of possible enzymes is largely empirical, because besides their classification, from which mechanistic information on the catalytic and substrate specificity may be derived, there are many other factors, including sensitivity to endogenous inhibitors, the presence of carbohydrate-binding module(s), and degree of selectivity towards soluble versus insoluble substrate, that play a role in determining the functionality of the enzyme. Moreover, their classification is not sufficient to predict their activity relating to breakdown of arabinoxylans because the mechanisms underlying their substrate selectivity remain unclear. Thus, the determination of the ability of a particular type of xylanase to provide beneficial effects in baked products is clearly an unexpected result.

In addition, it is unexpected that the claimed family 8 psychrophilic xylanases are more advantageous than family 11 xylanases in baking processes, and the skilled person would not have foreseen these unexpected properties. Thus, one of ordinary skill in the art would clearly not have any reasonable expectation that the presently claimed family 8 xylanase compositions and methods could be successfully used in baked products. Moreover, the unexpected results obtained with the claimed compositions and methods are neither disclosed nor suggested by any of the cited references, and could not have been predicted by one having ordinary skill in the art.

R1 discloses the addition of several types of enzymes to dough to improve the shelf life of the resulting breads during storage. One of these enzymes is Pentopan Mono BG, a purified endo 1,4-beta-xylanase (pentosanase) which is a family 11 xylanase. Although this enzyme promoted an increase in the firmness and elasticity of bread crumb, this reference also teaches that “[a]ddition of either pentosanase or a blend of pentosanase and lipase to dough did not have a clear, positive effect on the quality and staling rate of white, lidded-pan bread.” (p.398, second column, second paragraph). In addition, this reference notes that among the few used, not all enzymes exhibiting xylanase activity work the same, with some showing better results than others (see p.394, second col., last paragraph). Thus, due to the variation in the effectiveness of xylanases, one skilled in the art would not have a reasonable expectation that the xylanases recited in the present claims would be effective. Furthermore, R1 neither teaches nor suggests addition of a family 8 xylanase as presently claimed.

R2 discloses a xylanase isolated from *P. haloplanktis*. However, this reference neither discloses nor suggests the use of such enzymes in baked products. In fact, as acknowledged by the Examiner at page 3, section 9 of the Office Action, neither R1 nor R2 provides motivation for using the presently claimed psychrophilic xylanase in baking processes.

R3 discloses a long list of psychrophilic enzymes (see page 103, last paragraph), and discusses in general terms the potential applications of such enzymes in biotechnology. Although this reference discloses that xylanases can be used in baking processes to improve various properties of baked products, the section entitled “Food industry” quoted by the Examiner (p. 106, second column, lines 4-15), states that “[H]owever, there is no direct correlation between enzyme activity and functional efficiency, (...)”. As discussed below,

out of all of the known enzymes with xylanase activity, only a few within one family of xylanases has been applied for use in the baking industry. Thus, the broad generic disclosure that xylanases can be used in the baking industry in no way discloses or suggests whether a particular xylanase, such as the family 8 xylanase as presently claimed, would be effective when used in baking processes. Moreover, contrary to the Examiner's assertion that the skilled person would be motivated by R3 to use psychrophilic enzymes, not all psychrophilic enzymes are effective in this regard.

R4 discloses, in general terms, the addition of numerous enzymes encapsulated or coated by a lipid substance, including xylanases, to dough compositions. However, this reference neither discloses nor suggests any specific xylanase, or family 8 xylanases as presently claimed. Moreover, R4 does not provide a reasonable expectation that the xylanases recited in the present claims would be effective in bread improver compositions.

Based on the above discussion, Applicants submit that the combination of R1 to R4 would not lead the skilled person to the presently claimed invention for at least the reasons discussed above.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a)

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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### **CONCLUSION**

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below..

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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